Monica Healthcare

AUG 30 2011

# 510(k) Summary

## Monica IF24 CTG Interface Device

**Submitters Name:**

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Nottingham NG1 1GF
UK

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**Name of Device:** Monica IF24 CTG Interface Device

**Manufactured by:**

Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

**Date of Summary:** 12 August 2011

**Classification Name:** 21 CFR 884.2740 System Monitoring Perinatal

**Product Code:** OSP

**Secondary Product Code:** HGM

**Predicate Device:** Monica AN24 (K101801)
Philips Avalon CTS (K023931)

**Reason for 510(K):**
This 510(K) is to add the Monica IF24 Interface device as an accessory to the Monica AN24 Fetal Monitor previously granted market clearance under K101801

**Device Description:**
The Monica IF24 CTG Interface Device is an interface device that allows an AN24 to send data to a standard Fetal Monitor. The Monica AN24™ is a small, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) from the fetal electrocardiogram (fECG) and Uterine Activity (UA) from the Electrohysterogram (EHG) during pregnancy and can be used at any time from > 36 completed

weeks gestation in laboring patients. The AN24™ is suitable for singleton pregnancies only.

**Indications for Use:**

The Monica IF24 CTG Interface Device is an accessory to the Monica AN24) which provides a means of interfacing the wireless output of the Monica AN24 to the transducer inputs of a CTG Fetal monitor. The Monica IF24 CTG Interface Device enables signals collected by the Monica AN24 to be printed and displayed on a CTG Fetal Monitor and sent on to a central network, if connected. The device is intended for use by healthcare professionals in a clinical setting.

**Technology Characteristics:**

The Monica IF24 CTG Interface Device is a small, low-voltage device that receives the monitored parameters from the Monica AN24 Fetal Monitor and converts the wireless digital signal to analogue for inputting into a CTG Monitor. It has a touch screen for:

- Selection of the appropriate CTG monitor
- Calibration with the CTG Monitor
- Display AN24 battery power
- Display Bluetooth connectivity between the AN24 & IF24

The technological characteristics of the Monica IF24 CTG Interface Device are the same in design, material, principle of operation and energy source as the predicates.

The Monica IF24 CTG Interface Device has the same technological characteristics as the base station for the wireless transducers in the Philips Avalon (K023931) predicate device. Both technologies have the same principle of operation and energy source, including

- CPU (Microprocessor
- LCD
- Base station communication
- EEPROM
- Flash memory
- Clock generator
- RF Transmitter (Bluetooth)

**Non Clinical Test Summary**

The Monica IF24 CTG Interface Device and Accessories comply with voluntary standards. The standards were employed in the following areas:

- Electrical Safety
- EMC
- Material Safety
- Software Validation
- Usability

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**Conclusion**

The non clinical tests used voluntary standards to demonstrate that the Monica IF24 CTG Interface Device is as safe and effective in performance to the predicate device, the main standards employed were

- EN60601-1 electrical safety
- EN60601-1-2 EMC
- FCC CFR47 EMC
- EN 62304 – Software
- IEC 62366 Usability
- ISO10993 - Biocompatibility
- ISO13485 - QMS

The Monica IF24 CTG Interface Device has been subjected to the above non clinical tests combined with software validation and performance bench testing to demonstrate that the Monica IF24 CTG Interface Device accurately receives and transmits the correct data.

The conclusions drawn from the nonclinical tests, performance tests and the validation demonstrate that the Monica IF24 CTG Interface Device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Monica Healthcare
% Mr. William Sammons
Senior Project Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road
Unit B7
TWINSBURG OH 44087

AUG 30 2011

Re: K112163
Trade/Device Name: Monica IF24 CTG Interface Device
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: OSP, HGM
Dated: August 17, 2011
Received: August 18, 2011

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

**510(k) Number (if known):** K112163

**Device Name:** Monica IF24 CTG Interface Device

**Indications For Use:**

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112163